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**Title: Non-invasive vibrometry-based diagnostic detection of acetabular cup
loosening in Total Hip Replacement (THR)**

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Abstract

Total hip replacement is aimed at relieving pain and restoring function. Currently, imaging techniques are primarily used as a clinical diagnosis and follow-up method. However, these are unreliable for detecting early loosening, and this has led to the proposal of novel techniques such as vibrometry. The present study had two aims, namely, the validation of the outcomes of a previous work related to loosening detection, and the provision of a more realistic anatomical representation of the clinical scenario. The acetabular cup loosening conditions (secure, and 1 and 2 mm spherical loosening) considered were simulated using Sawbones composite bones. The excitation signal was introduced in the femoral lateral condyle region using a frequency range of 100–1500 Hz. Both the 1 and 2 mm spherical loosening conditions were successfully distinguished from the secure condition, with a favourable frequency range of 500–1500 Hz. The results of this study represent a key advance on previous research into vibrometric detection of acetabular loosening using geometrically realistic model, and demonstrate the clinical potential of this technique.

Keywords:

Acetabular cup loosening, Non-invasive diagnosis, Vibration analysis, Loosening diagnosis.

1. Introduction

Total hip replacement (THR) is aimed at relieving pain and restoring function. The procedure has come a long way since it was introduced by Charnley in the early 1960s, and was nominated as the operation of the century [1]. The high success rate of THR has contributed to the rapid increase in its use, with well over one million operations performed annually worldwide [2]. However, approximately about 4%–10% of all the involved implants are expected to fail in their first decade [3, 4], mostly due to aseptic loosening, which has been identified as the primary THR failure factor since 1979 [5]. Currently, imaging techniques are the primary diagnostic and follow-up method used clinically. These have, however, been shown to be unreliable for early loosening detection [6-8], especially of the acetabular cup [9]. The situation has led to the proposal of novel techniques such as vibrometry.

Vibration analysis is a mechanical non-destructive testing technique that is widely used in the inspection of composite materials and assessment of structural integrity, and has been successfully extended to the field of biomechanics [9, 10]. Vibrometry predominantly involves the measurement of the response to low-frequency excitation, as reflected from the target surface or structure [11]. Long bone property assessment, fracture healing monitoring, osseointegration, and stability monitoring are some of the applications of vibration analysis in biomechanics [9]. However, the most widespread use was initially in the field of dentistry, following the pioneering works of Meredith *et al.* [12, 13]. Since then, many research groups have used vibration analysis to detect prosthetic loosening through different measurement and excitation techniques [14].

Despite acetabular cups having a higher revision rate compared to femoral components, according to various national registries [15-19], the majority of published work on the use of

vibrometry for the diagnosis of loosening [7, 20-26] are femoral stem-related. Others have explored the detection of acetabular cup loosening [6, 9, 23] and were able to distinguish it from the stable condition, but did not define the detected level of loosening. Moreover, while the findings of a preliminary study [27] using Sawbones blocks substantiated the validity of the vibrometry approach, the complex geometry of the hemi-pelvis was not taken into consideration. The present study thus had two aims: i) to validate the outcomes of a previous study [27] related to the detection of loosening, and ii) to provide a more realistic anatomical representation of the clinical scenario through the development of an acetabular cup loosening model using a composite Sawbones femur and hemi-pelvis bones.

2. Materials and Methods

The loosening conditions of the acetabular cup were simulated using a composite femoral and hemi-pelvis bones (Femur 3406, Hemi-pelvis 3405, Sawbones Europe AB, Malmö, Sweden), a 44-mm stem (Exeter TM V40 TM, 28 mm standard head, Stryker Orthopaedics, USA), and a 56-mm cup (Trident® Hemispherical Cup, Stryker Orthopaedics, USA). The composite femur articulated with the hemi-pelvis that accommodated the loosened acetabular cup. The simulated conditions were 1 mm press-fit (secure condition), 1 mm spherical loosening, and 2 mm spherical loosening (Figure 1).

The 1 mm press-fit condition included a computer numerical control machined cup cavity of diameter 55 mm and depth 28.5 mm. A Stryker cup of diameter 56 mm was inserted through repeated impacting by a soft mallet until it was fully seated, in accordance with the existing literature [28-30]. The two spherical loosening conditions with gaps of 1 and 2 mm were simulated using machined hemispherical cavities of diameters 58 and 60 mm respectively, including a 5 mm wide channel of depth 3 mm in the lower cavity surface, used to control the

silicone thickness. The loosening gaps were filled with a silicone layer (EVO-STIK, Bostik Limited, England) in accordance with previous practise [10, 21, 31] to replicate the soft fibrous interface between the surfaces of the cup and bone. The silicone thickness was controlled using two 56-mm Nylon 66 domes (RS Ltd. Northants, UK) with different extended stem lengths of 4 and 5 mm, respectively. The domes were fixed inside the cup cavity channel (length 3 mm) for 24 h to cure the silicone (Figure 2).

The Exeter stem was cemented into the fourth-generation femur composite bone, in accordance with the manufacture's recommended surgical protocol. The femur was subsequently attached to the pelvis with springs to replicate the attachment muscles, as previously adopted by Rieger *et al.* [9]. Two springs with a spring constant of 2.26 N/mm, were respectively used to simulate the adductor magnus and adductor longus, while the gluteus medius muscle was simulated by two springs with a spring constant of 4.17 N/mm.

Two test mediums were used in this study. One set of tests was conducted in water to simulate the soft tissue surrounding the femur and pelvis, while the second set was conducted in air using a foam supports (Figure 3). The water medium was used in replication of the work of Rowlands *et al.* [32] to investigate its effect on the ultrasound readings. In the case of the air medium, two accelerometers were used together with the ultrasound probe to determine the optimal response measurement location.

2.1 Excitation Signal

The excitation signal was introduced at the femoral lateral condyle with a frequency range of 100–1500 Hz in increments of 25 Hz and a constant amplitude of 4 Volts (peak-to-peak) using a mini-shaker (V201, Ling Dynamic Systems Ltd, UK). That was driven through a

function generator (TG230, Thurlby Thandar Ltd, UK) via a power amplifier (PA25E, LDS Ltd, UK). The excitation method, input signal characteristics, and frequency range were adopted from previous works [20-23, 32], which highlighted the suitability of detecting implant loosening using a frequency sweep range below 1500 Hz.

2.2 Measurement and Analysis

The measurement instruments used for the two test mediums were different. In the case of the water medium, only the ultrasound probe was used, and it was positioned facing the anterior superior iliac spine (Figure 3b). In the case of the air medium (foam support) test, two accelerometers (Model 353B18, PCB Piezotronics Inc, Depew, NY, US) and an ultrasound probe (Mini Dopplex 500 4 MHz, Huntleigh Technology PLC, Cardiff, UK) were used (Figure 3a). The ultrasound probe and one accelerometer were coupled at the iliac crest, whereas the second accelerometer was located at the greater trochanter of the femur. Two accelerometers were attached to the surface of the Sawbones by screws using threaded steel inserts (PEM® Inserts, UK) for additional stability. The ultrasound probe was positioned on the Sawbones and supported using a laboratory stand, and an ultrasound gel (Aquasonic 100, Doppler size 60g, Huntleigh Technology PLC, UK) was employed between the probe and Sawbones surfaces for the air medium only.

Three composite hemi-pelvises and one femoral Sawbones were used to obtain ten sample readings for each simulated condition (1 mm press fit, 1 mm spherical loosening, and 2 mm spherical loosening). The hemi-pelvis was Velcro-coupled (VELCRO® Brand Heavy Duty, Polyamide) with the foam support material (Neoprene Foam, durometer value 15A–20A). The Sawbones femur medial epicondyle was also foam-supported rather than clamped [21,

22] or counterbalanced by weights [32]. After each reading, the system was disassembled and reassembled based on the marks on the composite bone and the holding table.

The characteristics used to diagnose THR loosening by vibrometry are mainly dependent on the frequency analysis of the targeted system based on the magnitudes of the primary frequency and related harmonics. This was completed with the aid of the spectrum analysis tool in the LabVIEW sound and vibration package (Signal Express, Suite version 11, National Instruments). The harmonic ratio was used to better illustrate the relationship between the harmonics and the fundamental frequency over the entire driving frequency range. At each response to the driving signal frequency, the magnitude of the resultant harmonic was divided by the main fundamental frequency of the response. The obtained harmonic ratios were numbered based on the number of harmonics used.

2.3 Statistics

The data normality was tested using the Shapiro-Wilk test. Based on the results of these tests, a non-parametric analysis was adopted for comparisons at each excitation frequency. A Kruskal-Wallis test was performed among the three simulation conditions (1 mm press-fit, 1 and 2 mm spherical loosening); in cases of significance, this was followed by Mann-Whitney U-tests. All statistical analyses were conducted using SPSS (IBM SPSS Statistics 20.0, IBM Corporation, Armonk, NY, USA), with the significance level defined as $p < 0.05$.

3. Results

3.1 Harmonic Ratio

The harmonic ratios of the Sawbones femur hemi-pelvis system was calculated up to the third harmonic. The effect of the accelerometer location on the measurements and that of the water medium on the ultrasound ratio are examined in the following subsections.

3.2.1 Accelerometer

The accelerometer harmonic ratio was quantified for the first three harmonics with respect to the magnitude of the primary fundamental frequency.

The first harmonic ratio was obtained by dividing the magnitude of the first harmonic (F1) by the fundamental frequency for the simulated conditions. Comparison of the secure condition with the 1 mm loosening condition revealed that the first harmonic ratio of the latter was significantly higher at 18 driving frequencies (100–250, 400, 550–800, and 1100–1400 Hz) ($p < 0.05$) based on the femur accelerometer reading, and for 17 frequencies (100, 300, 400–450, 600–700, 950–1000, 1100–1400, and 1500 Hz) ($p < 0.01$) based on the pelvis accelerometer reading. The 2 mm loosening condition had a significantly higher harmonic ratio compared to the secure condition at 16 driving frequencies ($p < 0.01$) based on the readings of both accelerometers—100, 400, 600–700, and 900–1400 Hz for the pelvis accelerometer, and 150–250, 550–800, 1100, and 1200–1450 Hz for the femur accelerometer. Further, comparison of the two loosening conditions revealed that the first harmonic ratio of the 2 mm condition was higher than that of the 1 mm condition at 12 driving frequencies (200, 650–950, 1050, 1200–1250, and 1450 Hz) ($p < 0.01$) based on the pelvis accelerometer reading, and at seven driving frequencies (800, 1050, and 1250–1450 Hz) ($p < 0.05$) based on the femur accelerometer reading (Figure 4).

184 The second harmonic ratios were also examined to see whether they exhibited the same
185 pattern as the first harmonic ratios with regard to loosening. This was observed to be the case,
186 although the corresponding driving frequencies for the second harmonic ratios were lower.
187 Comparison of the secure and 1 mm spherical loosening conditions revealed that the
188 loosening condition initially had significantly higher second harmonic ratios at 16 driving
189 frequencies (100–250, 500–550, 650–750, 1050–1100, and 1200–1400 Hz) ($p < 0.05$) based
190 on the femur accelerometer reading, and at 11 driving frequencies (650, 900–1000, 1150–
191 1400, and 1500 Hz) ($p < 0.01$) based on the pelvis accelerometer reading. This was also true
192 for the 2 mm loosening condition, which had significantly higher second harmonic ratios ($p <$
193 0.05) compared to the secure condition at 14 driving frequencies (100–150, 650–750, 900–
194 950, 1050, and 1200–1450 Hz) based on the femur accelerometer reading, and at 13 driving
195 frequencies (450, 650–700, 900–1000, and 1100–1400 Hz) based on the pelvis accelerometer
196 reading. However, the harmonic ratios of the 2 mm loosening condition were significantly
197 higher than those of the 1 mm loosening condition for 12 and 15 driving frequencies based on
198 the femur and pelvis accelerometer readings, respectively ($p < 0.05$).

199

200 The third harmonic ratios exhibited the same pattern as the first and second harmonic ratios.
201 This was evident from a comparison of the 1 mm loosening condition with the 1 mm secure
202 condition, wherein the third harmonic ratios of the loosening condition were found to be
203 significantly higher for 16 driving frequencies (100–200, 400, 500–800, 1100, and 1250–
204 1400 Hz) ($p < 0.05$) based on the femur accelerometer reading, and 14 driving frequencies
205 (200, 550, 650–700, 950–1000, 1100–1400, and 1500 Hz) ($p < 0.01$) based on the pelvis
206 accelerometer reading. The 2 mm loosening condition had higher third harmonic ratios at 17
207 driving frequencies (300, 450, 550–700, 850–1000, and 1100–1400 Hz) ($p < 0.05$) based on
208 the pelvis accelerometer reading, and 10 frequencies (100, 200, 600–700, and 1250–1450 Hz)

($p < 0.01$) based on the femur accelerometer reading. Further, the 2 mm loosening condition had higher third harmonic ratios compared to the 1 mm loosening condition at six driving frequencies (1000–1050, 1250–1300, and 1400–1450 Hz) ($p < 0.01$) based on the femur accelerometer reading. Based on the pelvis accelerometer reading, the third harmonic ratios of the 2 mm loosening condition were significantly higher than that of the 1 mm loosening condition at 13 frequencies (250–300, 600–750, 850–950, 1050, 1200–1250, and 1450 Hz) ($p < 0.05$).

To summarize, the harmonic ratios determined by the readings of the two accelerometers (located at the femur and pelvis, respectively) for the three simulated conditions show that loosening can be simulated detected in specimens that replicate the complex geometry of the *in vivo* scenario.

3.2.2 Ultrasound

The ultrasound harmonic ratio was quantified for the two tested mediums, namely, water and air. The majority of the significant findings were within the frequency range of 500–1500 Hz; with less consistent differences occurring within 200–450 Hz range.

The pattern of the first harmonic ratios for the ultrasound measurements were the same as that for the loosening conditions; with increased loosening from 1 to 2 mm, the harmonic ratio also increased. Initially, in comparing the secure and 1 mm loosening conditions, it was found that the latter had significantly higher first harmonic ratios ($p < 0.01$) for eight driving frequencies (200, 400–550, 1000, and 1250–1300 Hz) in the air medium, and 16 driving frequencies (200, 300, 400–450, 550–600, 1000–1300, and 1400–1500 Hz) ($p < 0.05$) in the water medium. The 2 mm loosening condition had higher first harmonic ratios for 16 driving

234 frequencies (200–250, 600–700, and 900–1400 Hz) ($p < 0.01$) in the air medium, and 20
235 driving frequencies (550–15000 Hz) ($p < 0.05$) in the water medium. Further, the 2 mm
236 spherical loosening condition had higher harmonic ratios than its 1 mm counterpart at 19
237 driving frequencies (200–250, 650–700, and 800–1500 Hz) ($p < 0.05$) in the air medium, and
238 12 driving frequencies (550 and 650–1150 Hz) ($p < 0.01$) in the water medium (Figure 5).

239

240 The second harmonic ratios also enabled distinction among the different conditions at
241 frequencies that were closely related to those of the first harmonic ratios. Comparison of the
242 secure and 1 mm loosening conditions revealed that the latter had higher second harmonic
243 ratios ($p < 0.05$) for seven driving frequencies (200, 400–500, 1000, and 1300–1350 Hz) in
244 the air medium, and 12 driving frequencies (300–350, 450, 700, 1000, 1100–1300, and 1400–
245 1450 Hz) ($p < 0.05$) in the water medium. The 2 mm loosening condition also had higher
246 second harmonic ratios ($p < 0.05$) compared to the secure condition for 19 driving
247 frequencies in both mediums. Between the 1 and 2 mm loosening conditions, the latter had
248 higher second harmonic ratios at 20 driving frequencies (250 and 600–1500 Hz) ($p < 0.01$) in
249 the air medium, and 13 in the water medium (550–1150 Hz) ($p < 0.01$).

250

251 The third harmonic ratios likewise distinguished the three simulated conditions in both the air
252 and water mediums. Higher ratios were observed for the 1 mm spherical loosening condition
253 compared to the secure condition at seven driving frequencies (200, 400–500, 1000, 1250–
254 1300, and 1400 Hz) ($p < 0.05$) in the air medium, and 11 frequencies in the water medium
255 (300, 1000–1300, and 1400–1500 Hz) ($p < 0.05$). The 2 mm loosening condition also had
256 higher third harmonic ratios compared to the secure condition at 19 frequencies (200–250,
257 400–450, 600–700, and 900–1450 Hz) ($p < 0.01$) in the air medium, and 21 frequencies (350,
258 500–1300, and 1400–1500 Hz) ($p < 0.01$) in the water medium. Further, the third harmonic

ratios of the 2 mm loosening condition were higher than those of the 1 mm loosening condition for 20 driving frequencies (250 and 600–1500 Hz) ($p < 0.01$) in the air medium, and 16 frequencies (200, 350, and 500–1150 Hz) ($p < 0.05$) in the water medium.

To summarize, the ultrasound harmonic ratio analysis enabled distinction between secure and loosening conditions in both the test air and water mediums, as well as between loosening conditions of differing severities. The findings of the investigations indicate that 500–1500 Hz is a favourable frequency range for both mediums.

4. Discussion

Despite the fact that acetabular cups have a higher revision rate compared to femoral components [15–19], the majority of previous works on vibrometry loosening diagnosis [7, 20–26] are stem-related. Although the detection of acetabular cup loosening has been previously explored [6, 9, 23] and was able to distinguish it from the stable condition, the degree of the detected loosening was not defined. The two aims of the present study were to validate the outcomes of a previous work [27] related to loosening detection, and investigate vibrometry diagnosis using a more realistic anatomical representation of the clinical condition.

The simulation of acetabular cup loosening using a Sawbones femur and composite hemi-pelvis bone was an attempt to achieve a more realistic anatomical setup. The femoral bone was fixed in position with springs that simulated the muscle attachment of the hemi-pelvis, as adopted by Rieger *et al.* [9]. This enabled the positioning of the excitation source on the lateral femoral condyle in the manner primarily suggested by Rosenstein *et al.* [20]. Two

mediums, namely, water and air (with foam support) were considered for the ultrasound probe measurements in an acrylic tank.

In the case of the air medium, two accelerometers and an ultrasound probe were used to measure the output vibrations. Two accelerometers were used in order to determine the optimal location for measuring the frequency response. One was located at the greater trochanter of the femur, and the other at the iliac crest of the pelvis. The initially spectral analysis based on the readings of the two accelerometers for a frequency range of 100–1500 Hz suggested that 1 and 2 mm spherical cup loosening could be distinguished from a secure cup. Specifically, there was a decrease in the fundamental frequency and increases in the related harmonics with increasing loosening gap. The patterns of the harmonic ratios with respect to loosening also supported the results of previous case studies; an increase in the loosening gap induced an increase in the harmonic ratio, with most of the significant readings occurring within the frequency range of 500–1500 Hz. Comparison of the two loosening conditions with the secure condition revealed that there were slightly more significant differences between the harmonic ratios based on the femur accelerometer readings compared to the pelvis accelerometer readings. In comparing the two loosening conditions of 1 and 2 mm, the pelvis accelerometer indicated more significant differences between the harmonic ratios.

The ultrasound measurement was used to compare the water and air mediums. The ultrasound spectral analysis of the three simulated conditions revealed that cup loosening could be detected even when using a more complex Sawbones femur-pelvis setup compared to a previous study [27]. The determined ultrasound harmonic ratios indicated a favourable frequency range of 500–1500 Hz in both tested mediums. In the water medium, there were

generally more significant differences between the two loosening conditions and the secure condition.

The findings of this study substantiate those of a previous work [27] related to the diagnosis of acetabular cup loosening by vibrometry. When the cup-loosening gap was increased from 1 to 2 mm, the fundamental frequency decreased, while the harmonics increased within a certain frequency range. Further, the harmonic ratio consistently increased with increasing loosening. These observations agree with those of previous works [9, 23], which found that acetabular cup loosening could be detected by vibrometry. However, the present study differs from previous ones by defining the minimum degree of loosening that was reliably detected, namely, 1 mm spherical loosening, as well as the favourable detection frequency range, namely, 500–1500 Hz.

However, the present study has certain limitations that should be taken into consideration in interpreting the results. Firstly, the considered spherical loosening is actually a simplification of acetabular cup loosening. In addition, the tests focused on the use of vibrometry to diagnose cup loosening using a cementless acetabular component. There is the need for further study using different acetabular cup designs, including cemented cups, to better establish the reliability of vibrometry diagnosis for future clinical application. Furthermore, the present study did not investigate the distinction between cup loosening and stem component loosening or the influence of the liner wear. However, the present study was an initial step in assessing the feasibility of vibrometry for detecting acetabular cup loosening. Simplification was thus expedient in obtaining credible preliminary evidence of the merit of the technique for further study to consider a wider range of scenarios and address the

abovementioned limitations. Such further work is expected to provide more conclusive data that can be used to lay the foundation for a clinical study.

5. Conclusion

The findings of this study support those of previous works on the use of vibrometry to detect acetabular cup loosening, namely, a decrease in the fundamental frequency and an increase in the related harmonics with increasing loosening gap in an anatomically realistic model. This was also indicated by the harmonic ratios, which were observed to consistently increase with increasing loosening. This study differed from previous work by defining the loosening level detected, namely, 1 mm spherical loosening, and the favourable detection frequency range, namely, 500–1500 Hz. Further research is required to determine the lower detection limit for this vibrometry approach.

Ethical approval

Not required.

Conflict of interest statement

There are no conflicts of interest to declare.

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Figure captions

Figure 1: Simulation setup of loosened acetabular cup using a femur and hemi-pelvis composite bone system.

Figure 2: Procedure for mimicking 1 and 2 mm spherical loosening: a) Silicone was injected between the surfaces of the cup and Sawbones cavity, b) The silicon thickness was controlled using two Nylon domes, c) After 24 h, the acetabular cup was inserted into the Sawbones cavity.

Figure 3: Test setups for a) air medium, and b) water medium.

Figure 4: First harmonic ratios for the 1 mm press-fit, 1 mm and 2 mm loosening conditions based on the readings of the accelerometer located at the pelvis (a, c, and e) and femur (b, d, and f). All the conditions are compared in a and b, while the 1 mm press-fit and 1 mm loosening conditions are compared in c and d, and the 1 mm press-fit and 2 mm loosening conditions in e and f. * Mann-Whitney test, $p < 0.05$, $n = 10$.

Figure 5: First harmonic ratios for secure (1 mm press-fit), 1 mm and 2 mm loosening conditions measured by the ultrasound probe in air (a, c, and e) and water (b, d, and f). All the test conditions are shown in a and b, while c and d statistically compares the secure and 1 mm loosening conditions, and e and f compares the secure and 2 mm loosening conditions. * Mann-Whitney test, $p < 0.05$, $n = 10$.

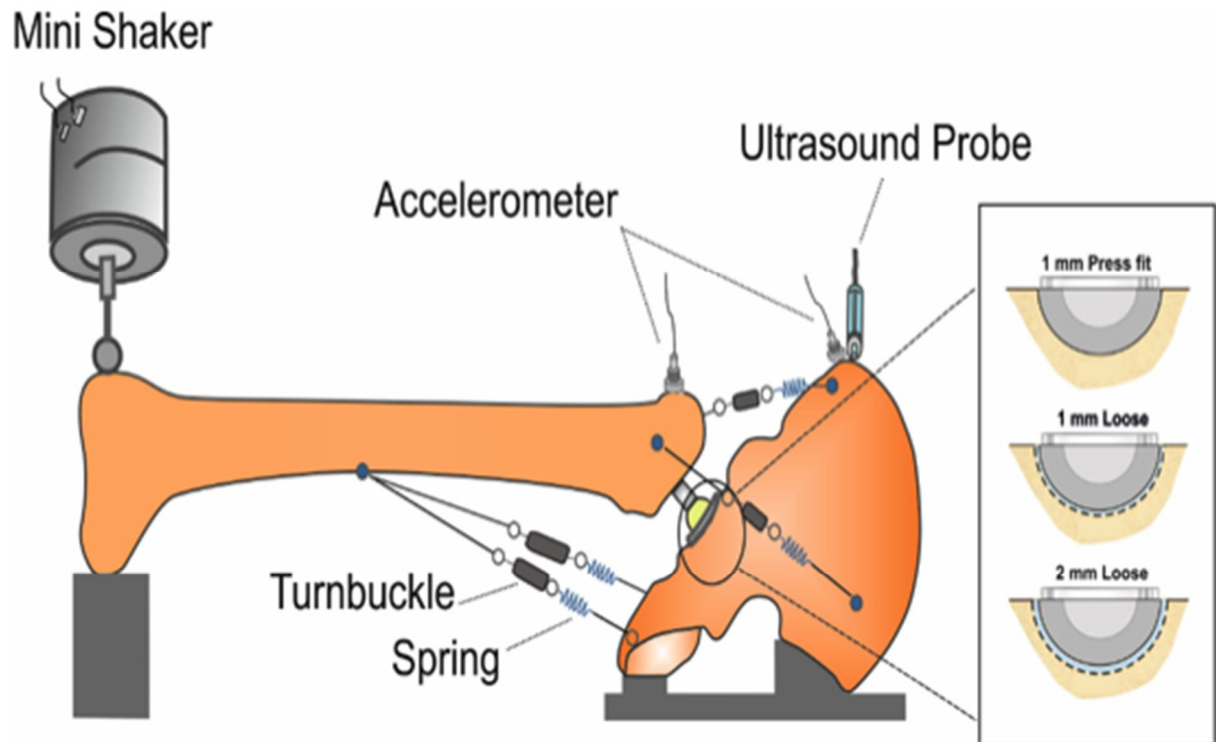
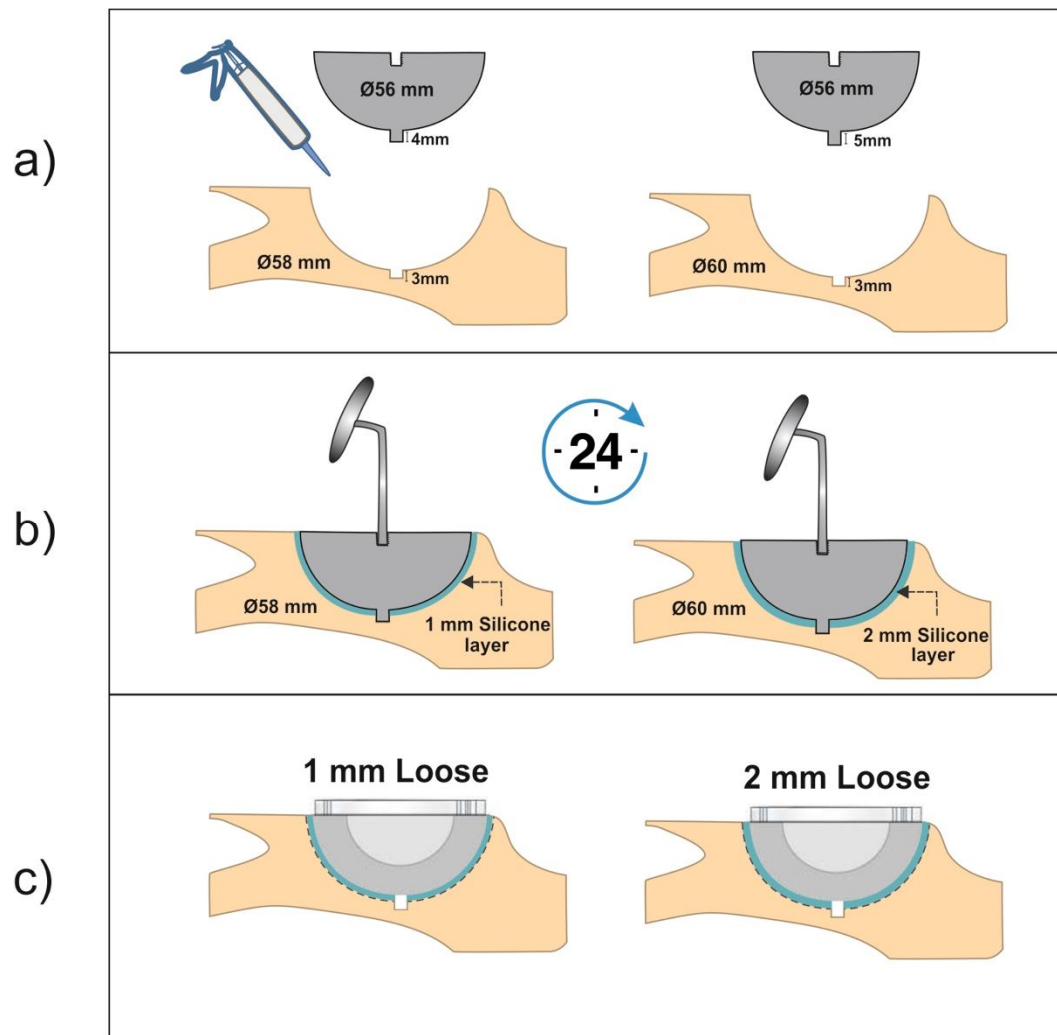


Figure 1: Simulation setup of loosened acetabular cup using a femur and hemi-pelvis composite bone system.

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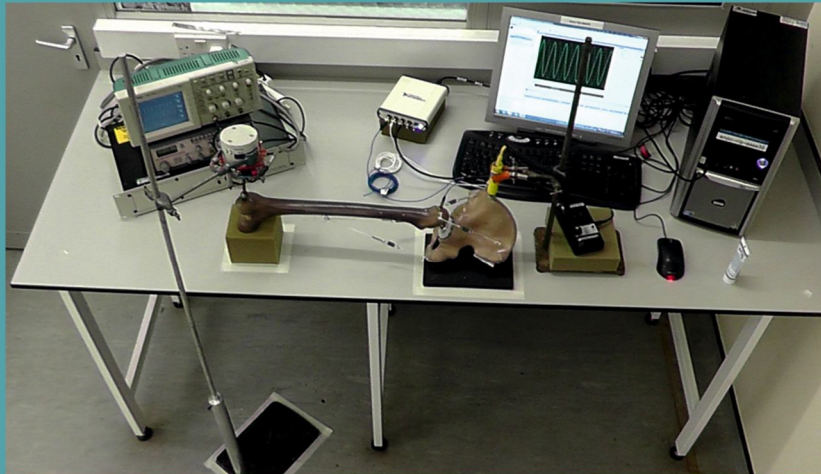
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486

487

a)



b)

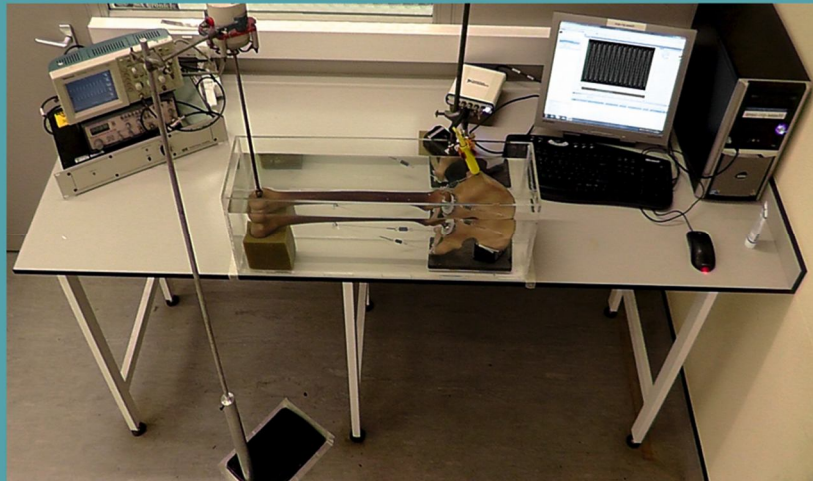


Figure 3: Test setups for a) air medium, and b) water medium.

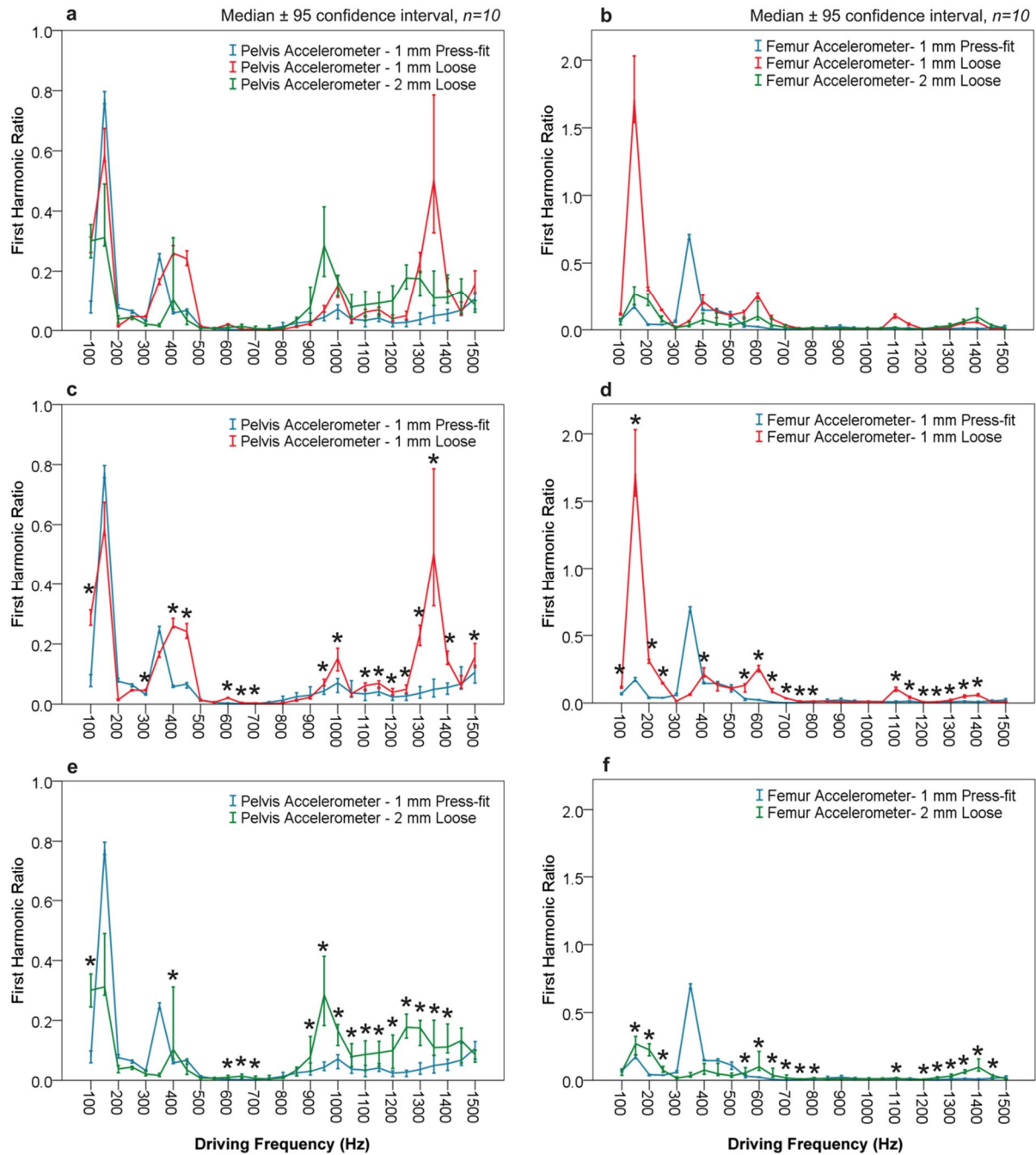


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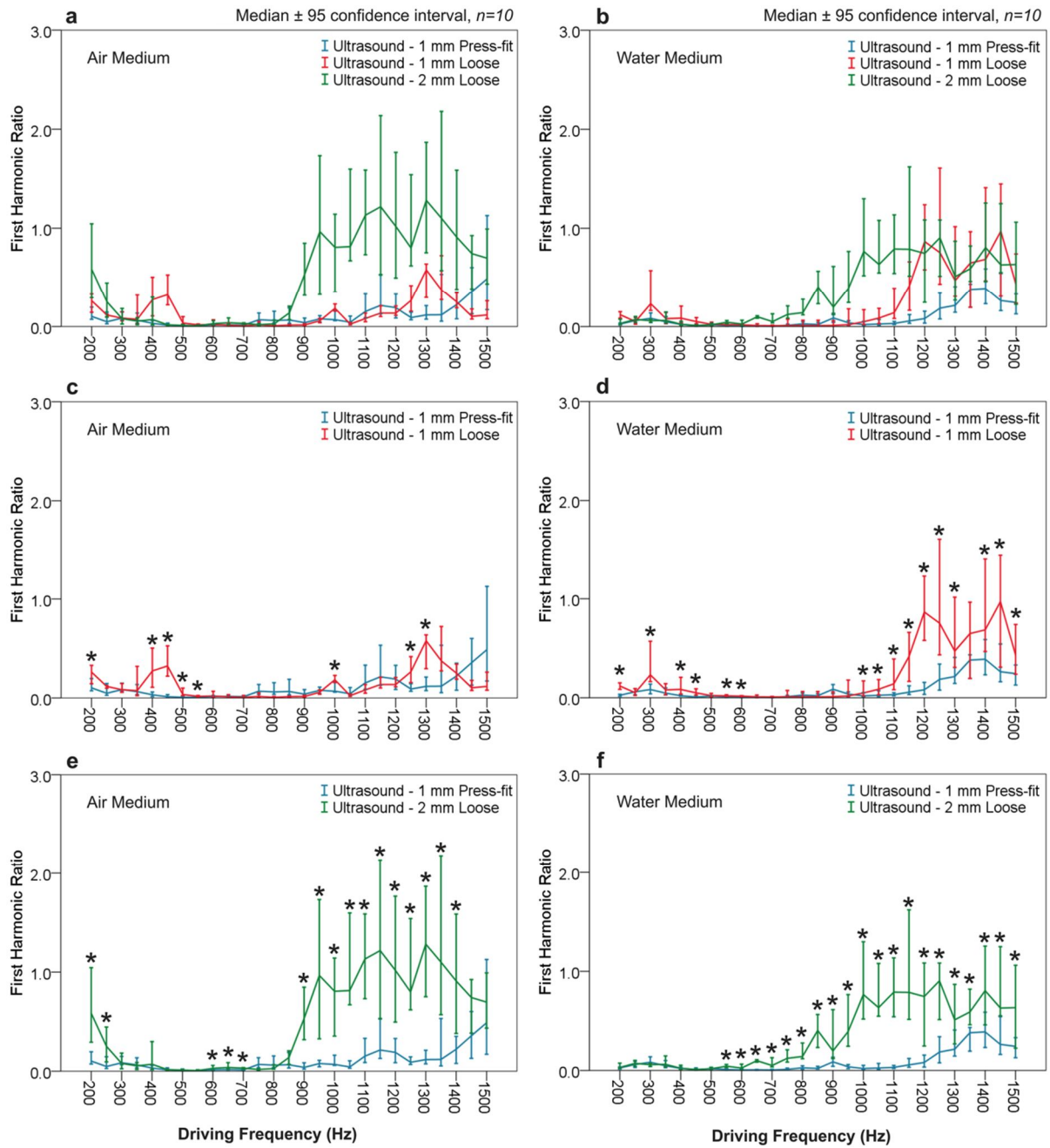


Figure 5: First harmonic ratios for secure (1 mm press-fit), 1 mm and 2 mm loosening conditions measured by the ultrasound probe in air (a, c, and e) and water (b, d, and f). All the test conditions are shown in a and b, while c and d statistically compares the secure and 1 mm loosening conditions, and e and f compares the secure and 2 mm loosening conditions. * Mann-Whitney test, $p < 0.05$, $n = 10$.